# Rapid HIV Testing FAQ

***Please note that information contained in this FAQ may NOT apply to non-Office of AIDS sites.***

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**If a client tests preliminary positive with an OraQuick blood test, will we be able to use the OraQuick oral fluid rapid test to confirm this result (or vice-versa)?**

**Will local health jurisdictions still be able to get and use standard testing, such as OraSure, and standard, laboratory-based blood testing?**

**If OraQuick is about to be approved for oral fluids, why should I get phlebotomy training?**

**Is it OK to use OraQuick in low risk settings?**

**How do I get OraQuick test kits?**

**How do I get control kits?**

1. **What are the requirements for doing OraQuick rapid HIV testing in California?**

   To conduct OraQuick rapid HIV testing, sites operating within the State Office of AIDS (OA) Counseling and Testing (C&T) program must: 1) be covered under a CLIA certificate, 2) have qualified personnel to conduct the testing, and 3) be able to perform quality assurance procedures outlined in the OA document "OraQuick Rapid HIV Testing Guidelines: Policies, Procedures, and Quality Assurance" (OA Rapid Testing QA guidelines).

   *IMPORTANT NOTE: Non-OA settings may develop their own QA guidelines in accordance with the manufacturer's instructions and federal and state requirements, including compliance with 17 CCR 1230, which applies specific requirements for HIV testing, and BPC 1206.5, which identifies California personnel requirements for conducting CLIA-waived testing.*

   *See http://www.cms.hhs.gov/clia/ for more information regarding CLIA, including contact information for regional offices.*

   *Contact Shui Land Kwong of Laboratory Field Services at (510) 873-6405 or skwong1@dhs.ca.gov for information regarding California requirements for conducting HIV testing.*

2. **What is a CLIA certificate?"**

   The Clinical Laboratory Improvement Amendment, or CLIA, is a federal regulation that controls how clinical tests may be conducted, including such things as quality assurance procedures, facility inspections, and qualifications and proficiency testing of personnel. When the FDA approves a clinical test, the test is assigned to a CLIA category, depending upon its complexity. The categories are "highly complex," "moderately complex," and "waived." CLIA applies different rules and requirements to a test depending upon its categorization/complexity.

   OraQuick is categorized as "waived" under CLIA, so to conduct OraQuick tests, a site must be covered under a CLIA Certificate of Waiver (COW) or higher. That is, sites covered under a CLIA certificate of moderate complexity (including provider-performed microscopy) or high complexity are also authorized to conduct CLIA-waived tests.

3. **If a test is "CLIA-waived," doesn't that mean that CLIA regulations don't apply to that test?**

   No. All laboratory tests are assigned a category under CLIA when they are FDA-approved. "CLIA-waived" is simply a category used for less complex tests. The CLIA requirements for waived tests are considerably less stringent than for moderate- or high-complexity tests, but CLIA regulations do apply to this category of tests.

4. **How do I get a CLIA certificate?**

   California Counseling and Testing Coordinators may arrange to cover all of the sites/settings in their area under a single CLIA certificate by using the "limited public health use" exception. Alternatively, each site may apply for its own CLIA certificate, or each subcontractor may cover one or multiple sites under a single CLIA certificate, provided the sites are not-for-profit.

   There are several advantages to utilizing the limited public health use exception. These include reduced expenses and paperwork, and consolidated administrative processes for applying and renewing a single certificate rather than several certificates. **More importantly, having a single individual act as the laboratory director ensures consistency of quality assurance procedures across multiple sites.**

   Requirements for obtaining a CLIA certificate of waiver include having a medical doctor to act as the laboratory director, completing the application materials, and paying the fee.

   Application materials and further instructions are available by clicking here.

5. **The public health lab director in my county is not interested in implementing rapid HIV testing. Can we still use OraQuick in our settings?**

Yes. OraQuick rapid HIV testing in OA counseling and testing sites does not require a public health laboratory director. A medical doctor such as the county health officer may be named as the laboratory director on the CLIA certificate of waiver for sites conducting OraQuick testing. This person is responsible for ensuring that quality assurance measures are conducted appropriately for all testing conducted under the auspices of that CLIA certificate, as outlined in OA guidelines and federal and state regulation. As a laboratory professional, the public health laboratory director may be an invaluable resource as an expert advisor for a CLIA-waived testing program, but this is not required.

**6. If I already have a CLIA certificate, can I use it to conduct OraQuick rapid HIV testing?**

OraQuick rapid HIV testing may be conducted in a setting with an existing CLIA certificate, provided the certificate covers the physical location where the testing will be conducted, and the laboratory director on that certificate agrees to provide oversight to the personnel performing the test and the procedures outlined in the OA Rapid Testing QA Guidelines. Note that the CLIA certificate specifies the physical location(s) that designate the laboratory, and tests may be performed *only* in that area. For example, if the existing certificate identifies the physical location of the laboratory as 200 Main Street, 2nd Floor, Room 202, *only* this room is covered under that certificate. (That is, this certificate would not cover testing performed in the clinic area on the first floor.) The certificate may be amended to cover the physical location where testing will be performed if all other requirements are met.

***Exceptions to the physical location requirement:*** Mobile testing units and temporary testing sites such as health fairs are automatically covered under the CLIA certificate of the "home base" site (i.e., the clinic or setting from which the mobile testing unit operates).

**7. My site has a moderately complex laboratory that runs all of our tests just down the hall. Can my counselors perform the OraQuick test under the auspices of that laboratory's CLIA certification?**

Maybe. If the laboratory director of that lab is willing to provide oversight to the counselors performing the test, and the procedures outlined in the OA Rapid Testing QA Guidelines, then that CLIA certificate can cover OraQuick testing performed by OA-trained counselors. However, oftentimes the director of a more traditional laboratory that operates with traditionally-trained laboratory personnel may not feel comfortable providing oversight to personnel such as counselors who typically do NOT have traditional laboratory training, and over whom the laboratory director may have no employment authority. In that case, a separate CLIA certificate may be the best alternative. Also, see answer to previous question, above, for physical location requirements.

**8. Can I apply for a CLIA certificate independently of my county C&T coordinator?**

Sites may obtain CLIA-certification independently of the county coordinator if it serves some purpose to do so, but must operate within the OA Rapid Testing QA Guidelines, and in cooperation with the C & T coordinator. Additionally, since the C&T coordinator must approve counselors to be sent for the required rapid testing training, cooperation between CBOs and C&T coordinators is essential.

**9. What are the requirements for personnel conducting rapid testing?**

***Single-session counseling:*** Existing counselors may provide single-session counseling after they have successfully completed the Rapid Testing CET – counseling portion. They must be up-to-date in other counselor training, including Basic I, Basic 2, and be current on CET. The counseling portion of the Rapid Testing CET qualifies as CET update training.

***Testing:*** Counselors (or other qualified personnel) may conduct OraQuick testing after they have successfully completed the Rapid Testing CET – testing portion. This portion includes instruction on operation of the test kit, selected quality assurance procedures, and a proficiency exam. See OA Rapid Testing QA Guidelines for competency evaluation procedures, which must be performed locally before personnel begin testing client samples.

***Sample Collection:*** Counselors (or other qualified personnel) must also be qualified to conduct necessary sample collection. Blood sample collection (including finger stick) requires phlebotomy certification. To conduct finger sticks, personnel are required to be certified as Limited Phlebotomy Technicians (LPT); Venipuncture requires certification as a Certified Phlebotomy Technician 1.

**10. Where can I find information on the phlebotomy requirements and trainings?**

For more information about California phlebotomy regulations and available training, see http://www.dhs.cahwnet.gov/ps/ls/lfsb/html/Phlebotomy.htm or contact Gwen Wong at (510) 873-6449 or gwong2@dhs.ca.gov.

*Please note that OA anticipates making a bulk purchase of a CD-ROM-based training module for Limited Phlebotomy Certification that will be available at no cost to local health jurisdictions on an as-needed basis. (Expected time frame for availability of this resource: Late December 2003-early January 2004.)* Contact Sandy Simms at (916) 449-5797 or Ssimms@dhs.ca.gov for details.

**11. Can CBOs that are directly funded by the CDC complete the CDC training for rapid testing?**

Yes, but sites that are not a part of the OA C&T program must also meet requirements for "non-OA" programs for conducting HIV tests, including CLIA certification, California Laboratory Licensing (including enrollment in an approved proficiency testing program), and personnel requirements. See answer to Question 1 of this FAQ for more details and resources for non-OA sites. Counselors that intend to provide counseling and testing in OA settings must successfully complete the OA Rapid Testing CET. Counselors that do not complete this CET or who are not operating within an OA C&T program are **NOT** legally qualified to conduct the OraQuick rapid HIV test (unless they independently meet the criteria outlined in BPC 1206.5).

**12. How do I schedule OA rapid test training for counselors in my settings?**

Contact your county C&T coordinator to schedule trainings. C&T coordinators should contact Sandy Simms at (916) 449-5797 or Ssimms@dhs.ca.gov to schedule trainings.

**13. How is single-session counseling different from counseling with standard lab-based testing?**

The primary difference is that both risk assessment and result disclosure occurs within a single counseling session. The implications of this include:

***All results delivered**:* Since results are delivered during the initial session rather than requiring a return visit, virtually all clients will receive their test results. Although preliminary positive results require a confirmatory sample and a repeat visit to receive confirmed results, early experience with rapid testing shows that most clients are highly motivated to return for results under these circumstances.

***Positive disclosures:*** All counselors must be willing and able to provide both positive and negative result disclosures. Since it is not possible to predict in advance which clients will test positive, all counselors conducting single-session counseling must be prepared to deliver a positive result with little warning.

***Increased intensity:*** Counselors with experience performing single-session counseling report an increased connection to the client, and an increased intensity to the counseling session. While this results in a more effective counseling session, it is also a source of additional stress for counselors, at least at first. However, counselors also report greater satisfaction from single-session counseling.

The OA rapid testing CET includes instruction, modeling, and role-playing for skills required to competently deal with these and other issues associated with rapid testing and single-session counseling.

**14. What quality assurance measures are required?**

Quality assurance requirements are thoroughly outlined in the OA Rapid Testing QA Guidelines. They include such things as monitoring the temperature in the test kit and control unit storage area, running controls to ensure that test kits are operating properly, and maintaining and reviewing records of QA activities to ensure the quality of the testing process. To be sure that a site has all quality assurance measures in place before beginning rapid HIV testing, use the Site Preparation Checklist that appears in the appendix of the guidelines.

**15. Where can I get quality assurance forms and other documents required for rapid testing?**

The OA Rapid Testing QA Guidelines includes QA forms and other documents in the appendix. Additionally, these forms are also available in the printable documents folder on the Rapid Testing Guidelines CD. Documents that may require editing for local use are also in available in the editable documents folder. The lab slip and CIF are available in pre-printed format. To order, contact Denise Humenik at (916) 449-5822 or Dhumenki@dhs.ca.gov.

**16. What kind of sample can OraQuick use?**

Currently (Dec 03), the OraQuick rapid HIV test is FDA-approved for use with finger stick and venipuncture blood samples. The manufacturer has submitted a request for FDA-approval for use with oral fluid samples. This decision is still pending.

**17. Do OraQuick positive results need to be confirmed?**

Yes. OraQuick is a screening test (like the ELISA). A reactive OraQuick result is considered "preliminary positive" until confirmed by a traditional laboratory Western Blot (WB) or IFA. At some point in the future it may be possible to conduct rapid confirmatory testing by using a second, different rapid test to confirm preliminary positive results, but for now confirmatory samples must be submitted to a traditional laboratory for WB or IFA testing. See OA Rapid Testing QA Guidelines for more details regarding confirmatory procedures.

**18. Can I use OraSure to do a confirmatory test?**

Yes, it is acceptable to use the OraSure sample collection device to collect an oral fluid sample to send to the lab for confirmatory testing. However, because oral fluid testing is *slightly* less sensitive than blood testing, it is preferable to conduct confirmatory testing with blood whenever possible. See OA Rapid Testing QA Guidelines for more details regarding confirmatory procedures.

**19. If a client tests preliminary positive with an OraQuick blood test, will we be able to use the OraQuick oral fluid rapid test to confirm this result (or vice-versa)?**

No. All rapid test preliminary positive results must be confirmed with a second, independent test that is FDA -approved for this purpose. The OraQuick rapid HIV test operates by the same mechanism (ELISA) regardless of whether the sample is oral fluid or blood. That is, these methods of testing are not "independent," and may not be used to confirm one another. In contrast, the OraSure sample collection device allows for the collection of an oral fluid sample, which may then be tested in a laboratory by two independent methods: ELISA and Western Blot. For this reason, an oral fluid sample that is sent to the lab for Western Blot testing may be used to confirm OraQuick preliminary positives, but oral fluid and blood OraQuick rapid tests may not be used to confirm one another.

**20. Will local health jurisdictions still be able to get and use standard testing, such as OraSure, and standard, laboratory-based blood testing?**

Yes. These testing methods will continue to be available for the foreseeable future.

**21. If OraQuick is about to be approved for oral fluids, why should I get phlebotomy training?**

FDA-approval for oral fluid use is pending. It may occur quickly, or it may encounter delays. If it encounters delays, only settings which have personnel qualified to collect finger stick blood samples will be able to begin rapid testing.

After the approval of OraQuick for oral fluid use, the need for phlebotomy training will become less urgent. However, the capacity for blood sample collection will continue to be valuable: Although OraSure oral fluid samples are acceptable for confirmatory lab testing, blood testing is slightly more sensitive, and will result in fewer "discordant" results. Additionally, the eventual availability of a rapid confirmatory test will almost certainly require the ability to collect finger stick blood samples. Sites that do not have this capability will not be able to offer rapid confirmatory testing when it becomes available.

**22. Is it OK to use OraQuick in low risk settings?**

The OraQuick test remains accurate even in low-risk settings – that is, the rate of inaccurate results, or "false positives" remains the same regardless of setting. However, because of the lower rates of true positives, the proportion of true positives to false positives will be lower when used to test low risk populations. (For further explanation of this concept, click here.)

However, testing in OA C&T programs is intended to be targeted to populations at highest risk for HIV. Because there are simply not enough public health resources to test everyone who may have some minor risk for HIV, the only way to accomplish the public health mission of reducing the spread of HIV is to target the limited resources available in ways that will maximize their impact. Providing C&T services to positive and high-risk negative clients serves to reduce the likelihood that they will contract or transmit HIV. Resources expended to provide services to low-risk populations, while providing peace of mind to the client, do little to reduce the spread of HIV.

**23. How do I get OraQuick test kits?**

First, contact Sandy Simms at (916) 449-5797 or Ssimms@dhs.ca.gov to find out if kits are available from the CDC at no cost. If not, purchasing may be done directly through OraSure Technologies, Inc. Customer service information is available at http://www.orasure.com.

**24. How do I get control kits?**

First, contact Sandy Simms at (916) 449-5797 or Ssimms@dhs.ca.gov to find out if control kits are available from OA at no cost. If not, purchasing of control kits may be done directly through OraSure Technologies, Inc. Customer service information is available at http://www.orasure.com.